State Pharmaceutical Assistance Transition Commission Meeting

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Centers for Medicare and Medicaid Services

Held at the
Holiday Inn
415 New Jersey Avenue, NW, Washington, DC
Thursday, October 14

Meeting Summary

(9:12 a.m.)

*Writer's queries -- **{{<u>double-bracketed, italicized, bolded, underlined text</u>}}***

***Some recommendations/statements are not followed by a "Q&A" section—in these cases, there were no additional comments on the recommendations/statements in the writer's notes.*

Participants

State Pharmaceutical Assistance Transition Commission present: Joan F. Henneberry (Chair), Clifford E. Barnes, Esq.; James Chase; Jay D. Currie, PharmD; Janice O. Faiks, JD; Dewey D. Garner, PhD; Laurie Hines, JD; Julie A. Naglieri; Mary Liveratti; Anne Marie Murphy, PhD; Dennis O'Dell; Robert P. Power, MBA, CBES; Susan C. Reinhard, RN, PhD; Sybil M. Richard, JD, MHA, RPh; Elizabeth J. Rohn-Nelson, consumer representative; Marc S. Ryan, MPA; Linda J. Schofield, BSN, MPH; Martin Schuh, MBA

Others present: Marge Watchorn, Deirdre Duzor, and Katiuscia Potier, CMS; Roy Bussewitz; John Coster; Stephen Crystal, PhD; Kristen Engleheart; Linda Flowers, Kimberley Fox, MPA; Evelyn Gooden; Jack Hoadley, PhD; Kathleen Mason; Tom Morrison, RPh; about 25 interested persons

Welcome Attendees and Review of Meeting Agenda and Process

Ms. Henneberry, Chair, State Pharmaceutical Assistance Transition Commission (SPATC), called the meeting to order at 9:10 a.m. and explained the how the meeting would proceed. Following a brief of description of the history of the commission and the overarching principles guiding the commission's charge, one commission member will walk through the commission's preliminary recommendations associated with each subcategory under three main topics: eligibility and enrollment, drug coverage and service delivery, and coordination of benefits. Miscellaneous recommendations and issues still to be resolved also will be

presented. Commission members and others in attendance will be invited to ask questions and comment on the presentation of key issues and recommendations in each subcategory. At the end of the day, the audience will be asked for additional questions and comments. Ms. Henneberry will provide a final wrap-up prior to adjournment of the open session of the meeting.

Formal Introductions—SPATC members and Visitors

Commission members and members of the public present in the audience introduced themselves, noting their affiliation and background or area of interest.

Review of SPATC Mission, Charge, and Activities

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required the Secretary of the U.S. Department of Health and Human Services (DHHS) to establish a State Pharmaceutical Assistance Transition Commission. The commission was founded to help ensure that low-income beneficiaries who currently receive drugs through the state will continue to get drug benefits without additional paperwork, pursuant to Medicare Part D. Commission members were drawn from a broad range of backgrounds and expertise to be able to address all questions facing the commission in implementing the new law effectively. The commission is charged with developing a proposal (including any specific legislative or administrative recommendations) to address the unique transitional issues facing State pharmaceutical assistance programs and program participants resulting from the implementation of the new voluntary prescription drug benefit program.

At the July 7, 2004, meeting of the commission, Secretary Tommy Thompson announced that the DHHS will release $125 million in grants, distributed to state assistance programs over the next 2 years. The grants will help ensure that low-income beneficiaries understand the new Medicare law and receive the best possible benefits under it. The Medicare drug card program enables seniors to group together to get prices that are 10 to 15 percent lower than the retail cost. Low-income beneficiaries will qualify for a $600 discount and wrap-around benefits, which will be fully implemented by January 1, 2006. The Centers for Medicare and Medicaid Services (CMS) is working on other programs for the 2006 implementation—for example, alternatives to drugs Medicare now provides—with the intent of providing real relief for beneficiaries in coordination with the states.

Analysis of the new law indicates that comprehensive benefits for seniors and low-income persons in addition to employer benefits will also benefit the states because it helps states defray costs. Nevertheless, states will face some new costs (e.g., “claw-back” provisions, and additional beneficiaries, as more people may sign up for benefits and services). Commission members are needed to ensure that the law will be implemented as intended, without interruption of benefits and care. One provision of the new law is that the program must be running effectively within the next year and a half. In the course of addressing these issues, members were asked to examine and determine, to the extent possible, how the enrollment process can be simplified, what processes state programs need in order to evolve, and what will help the agency and Congress to make the transition happen as smoothly as possible. For Part D, health care providers and policy makers can build on the experience gained from implementing the prescription drug card program.

To date, the commission has been examining different ways in which the states can develop a single point of contact, and how states can wrap-around new benefits. Members of the commission worked in three subcommittees to discuss and identify key issues, barriers, gaps in the areas of beneficiary transition, coverage and access, and claims/payer. Recommendations generated from the workgroup discussions and deliberations were presented to the full commission and the public during the October 14, 2004, meeting. The initial recommendations will be developed further and finalized based on questions and comments made by commission members and guests at the meeting.

The commission's final report will be submitted to the President and the Congress by January 1, 2005.

July 2004 Commission Meeting

The first public meeting of the SPATC was held on July 7, 2004, in Washington, DC. The meeting agenda included public testimony, presentations on independent research on existing state prescription drug programs, and an open session for guests to offer further comments and statements. The meeting continued on July 8, 2004, with a closed session of the commission, which broke into three working groups. The Beneficiary Transition Workgroup focused on consumer issues and program redesign of state pharmacy assistance programs (SPAPs). The Coverage and Access Workgroup focused on logistics and implementation of the new program, specifically, what will the SPAPs look like? The Claims and Payer Workgroup focused on systems infrastructure, information exchange issues, and key components of prescription drug plans (PDP) and SPAP programs.

Members of the respective workgroups identified gaps, needs, barriers, and other critical issues pertinent to the topics of the groups. Recommendations were based on how well they related to SPAPs and to the guiding overarching principles. Decisions on recommendations were made by consensus, and the workgroups worked to resolve conflict and reduce redundancy in developing the set of preliminary recommendations.

Overarching Principles

The ultimate goal of the redesigned SPAPs is to assure that SPAP members have uninterrupted access to medications. This goal may be achieved through creation of a framework that makes it easy for SPAPs to coordinate with PDP sponsors. Key features of that framework include encouraging state flexibility and choice and minimizing cost shifting to SPAPs. Implementation of the new program should strive for seamless coordination of benefits, real-time information exchange, minimization of paperwork, and maximization of technology. Parties should apply lessons learned from implementation of the Medicare drug discount cards. Evaluation of the discount card program is not part of the commission's mission, but commission members wanted to build on the successes associated with the rollout of the discount cards. The final overarching principle is to acknowledge the enormous challenge of public education and marketing and the role for SPAPs in implementing the new law. Working together with all parties—advocacy groups, pharmaceutical companies, professional societies and organizations, local and state health entities, CMS, and others—will be integral to the success of this effort.

Commission Recommendations: Eligibility and Enrollment

Susan Reinhard, Leader of the Beneficiary Transition Workgroup, noted that eligibility and enrollment represent the key entry points for beneficiaries into SPAPs. She pointed out that although Medicare is a Federal program, it relies on State-Federal partnerships. However, state programs vary considerably with respect to options and experience. A charge to the workgroup was to translate and simplify this complicated two-step process as much as possible. Workgroup members identified a range of factors that can affect entry into the system while developing their recommendations.

Eligibility Determinations

Recommendations

- CMS and the Social Security Administration (SSA) should explicitly state that SPAPs are permitted to make eligibility determinations for subsidy assistance for low-income persons who apply for benefits through the SPAP.
- The SSA should allow coordination of the eligibility determination and re-determination process, including use of SPAPs as contractors of the SSA and/or Medicaid. Through the sharing of electronic data on SPAP forms, both state and Federal programs can have the same information.

Q&A

- *Kim Fox* supported the recommendations and suggested that the commission recommend that CMS materials include a description of state-specific programs and SPAPs. SSA materials should also include information on SPAPs. She also inquired why the discount card didn't involve a two-step process.

Asset Determinations

The commission's recommendations in this category represent efforts to improve accessibility to and ease of being eligible for SPAPs. Many seniors do not have substantial assets, so running assets test could be an inefficient use of funds.

Recommendations

- The Medicare Modernization Act should be amended to eliminate the asset test for determining low-income subsidy eligibility.
- Until an amendment is signed into law, states should be permitted the same flexibility as they do with the Medicare Savings Program.
- Until an amendment is signed into law, CMS should eliminate life insurance policies and clarify that vehicles, which are mentioned in the preamble of the law, are not assets.
- CMS should determine the applicability of the asset test based on a cost-benefit analysis.

Marketing Materials

Mary Liveratti, workgroup member, noted that there has been considerable confusion regarding the discount drug cards rolled out last spring. The commission wants to simplify Part D to avoid the confusion seen before.

Recommendations

- A PDP sponsor's marketing materials and forms should include information about coordination of benefits with SPAPs. Such information may include premium costs, coverage gaps, and portions paid by the states.

- Marketing materials should also be available in other languages, as appropriate.

Automatic Enrollment
Susan Reinhard noted that recommendations regarding automatic enrollment are consistent with several of the overarching principles identified by the commission, including expansion of drug coverage, facilitation of coverage through SPAPs, and simplification of the program. Regulations allow for enrollment through a variety of vehicles, including SPAPs.
Recommendations

- SPAPs should be considered authorized representatives of their beneficiaries for purposes of applying for assistance and enrolling in plans.
- SPAPs should be permitted to select one or more preferred plans, with an opt-out provision.
- SPAPs should be allowed to enroll members into one or more preferred plans and pay premiums on behalf of their beneficiaries.

Q&A

- *Kathleen Mason* commented that the NJ SPAP has simplified the two-step process somewhat in that if the state can determine eligibility, it then proceeds directly to enrollment.
- *Robert Power* commented on the ability of SPAPs to declare preferred PDPs. He noted that experience with the discount drug cards supports this option for SPAPs. He added that the Minnesota SPAP has received considerable positive feedback from private companies about working with the state program. *Marc Ryan* appreciated Robert's comments because of difficulties Connecticut was having trying to coordinate multiple vendors and state and Federal data and information in the discount card program. He cautioned that Part D enrollment is expected to be more complex; if CMS does not allow SPAPs to identify a preferred plan or plans, the states need to develop an alternative strategy.

SPAP Endorsement of Preferred Plan(s)
Susan Reinhard commented that New Jersey has used RFPs with state-targeted specifications that allow state programs a range of options on how to proceed with endorsing preferred plans.
Recommendation

- CMS should permit SPAPs to endorse a preferred plan. This recommendation simplifies choices to SPAP beneficiaries and encourages enrollment. It also allows states to obtain the best value and encourages continued participation. Finally, coordination of benefits (COB) will be improved, and the need to regulate COB will be relieved.

Q&A

- *Marty Schuh* noted that his company, ACS State Healthcare, is considering becoming part of the PDP system and may be able to achieve this goal by offering the state blocks of eligible enrollees.
- *Marc Ryan* pointed to anecdotal evidence of confusion about plan endorsements at all levels. For example, patients have been denied medications because they did not have their discount card in hand. He suggested that the number of PDPs should not be limited;

imposing limits can have serious real-life consequences for those in greatest need of these programs. This may also decrease the amount of administrative work for the state.

Non-discrimination

Cliff Barnes, workgroup member, explained that coexistence of PDPs with SPAPs provides money that isn't discriminating. Opt-out provisions protect beneficiaries, even with autoenrollment. The preamble of the act seems to go beyond the regulations, but the commission believes that the opt-out provision satisfies the regulation. The commission also believes that the states should have same process that the Federal government has through its dual-enrollment allowance.

Recommendations

- The opt-out provision protects beneficiaries' free choice of plans.
- The non-discrimination provision in the statute should be satisfied if SPAPs agree to pay an equal actuarial value for their members in all plans, not just a preferred plan.

Low-Income Subsidy

Robert Power, member of the Coverage and Access Workgroup, noted that SPAP members are not typical Medicare recipients. Capitation of payments transfers risk to beneficiaries, and although the regulations recognize some need for additional payment, they do not require such payments.

Recommendations

- Risk adjustment methodology must assure PDP sponsors of adequate reimbursement for low-income populations and recognize morbidity and utilization, enhanced benefits, and induced demand.
- Short-term incentives should be offered to PDP sponsors to enroll low-income persons.

Q&A

- *Susan Reinhard* stated that the commission wanted to ensure that private companies without experience with populations participating in SPAPs will not be disinclined from enrolling, for example, low-income persons.

Premium Payments

Recommendations

- SPAPs that pay Part D premiums on behalf of their members should to do so up front. A sliding scale is usually used for persons with incomes up to 125-!135 percent of the poverty level.
- An automated premium buy-in system needs to be in place before January 1, 2006. Such systems are expected to be similar to states' payments of Medicare Part B on behalf of beneficiaries.

Q&A

- *Marc Ryan* strongly supported these recommendations.

Late Enrollment Penalties

Regulations provide for a 1-percent-per-month penalty for eligible beneficiaries who do not sign up as soon as they can for the program. SPAPs are responsible for the first 20 percent of this penalty for up to 60 months [confirm in the regs…doesn't sound right.].

Recommendations

- The minimum late enrollment penalty should apply to SPAPs that pay premium costs, including late fee penalties, on behalf of their beneficiaries.
- Any late enrollment penalties should be waived for SPAP members during the first year of implementation of the new program.

Q&A

- *Susan Reinhard* noted that the commission would like to have additional discussions on the specifics of these recommendations. It wants to identify strategies to avoid late enrollments based on urgent needs of beneficiaries.
- *Anne Marie Murphy* suggested that most states likely have experience in this area and can identify seniors who are eligible and have great needs but do not have access despite outreach.
- *John* Coster suggested that outreach and education efforts to recruit eligible beneficiaries should be expanded. Pharmacists may be one group to target to do outreach. The commission may wish to recommend that some of the $125 million allocated for the state programs be used for education of providers and pharmacists. *Jay Currie* commented that through experience with the discount cards, the states learned that giving pharmacists the additional role of educator regarding SPAPs can prove difficult. Such a role can put a notable burden on pharmacists, who already help patients work through various components of the healthcare system and do extensive education on a range of issues important to patients. To what extent would pharmacists be involved in deciding on SPAP versus PDP formularies? What conflicts of interest are in play on the part of the pharmacists and the pharmacies? More general questions include how can messages be standardize, and who would develop these messages? Despite these challenges, the commission recognized that pharmacists play a unique role in healthcare delivery to SPAP beneficiaries. *Kim Fox* added that the role of pharmacists is even more critical in non-SPAP states than in SPAP states. The commission and the states need to look at pharmacists as *part* of the solution, not *the* solution, and to recognize pharmacists as an invaluable resource.
- Regarding a question about which entities are required to provide a minimum subsidy, *Linda Schofield* stated that PDPs are required to provide at least the minimum subsidy but MA-PDs are not.
- Commission members agreed that there are many more details to be sorted out on this issue. These questions and issues will be addressed in future commission meetings.

Commission Recommendations: Drug Coverage and Service Delivery

The Coverage and Access Workgroup developed recommendations for this category. Laurie Hines, workgroup member, opened the discussion with a focus on formulary issues by noting that the commission's recommendations are a response to CMS regulations allowing preferred and nonpreferred pharmacies to meet regional needs of beneficiaries. A potential drawback of this combinational approach is that it could discriminate against people in certain locales and, as a result, end up being cost prohibitive.

Network Design

Recommendations

- CMS should count only preferred pharmacies as part of a plan's network for the purpose of determining whether a plan meets CMS's access standards.
- CMS should require PDP sponsors to solicit any willing long-term care pharmacy in their region to join the network.
- CMS should more broadly define "long-term care facility" to include intermediate care facilities for persons with mental retardation (ICFs/MR), include intermediate care facilities for persons with developmental disabilities (ICFs/DD), assisted living, and other supportive housing facilities.

Q&A

- *John Coster* asked how "region" is defined and whether an SPAP can be offered in more than one state if, for example, a 90 percent of all beneficiaries are within 2 miles of a pharmacy but they also are split between two states. What are the standards, and do SPAPs need to meet all of them? The military provider TriCare takes a different approach by acting as a national program with a network of approximately 53,000 pharmacies that all members of the system may access. John suggested that the commission recommend clarification on the pharmacy access standards.
- *Kim Fox* expressed concern with issues raised in the preamble and how these issues do not always appear to be consistent with the regulations (e.g., preferred pharmacies, response to providers). Without further clarification of these issues, efforts aimed at pharmacy coordination will become increasingly complicated on multiple levels.

Mail Order

CMS proposed regulations allow for mail orders through PDPs and extended supplies at retail pharmacies, but the regulations don't take into account differential payments made by SPAPs for such purchases.

Recommendations

- CMS should ensure that the cost differential paid for extended supplies purchased at a retail pharmacy count toward "true out-of-pocket" costs (TrOOP).
- CMS should encourage PDP sponsors to have an exception process for seniors who have insecure mail boxes so that the cost differential between mail-order prescriptions and extended-supply prescriptions at retail stores is waived.

Q&A

- *James Chase* noted that the commission had extensive discussions on the feasibility of mail orders with SPAPs. Regarding questions about the issue of "secured" mail boxes, he commented that many SPAP beneficiaries, whose average age is between 78 and 80 years old, have no mail box or mail drop; thus, a process that ensures delivery/receipt of medications to this subgroup is needed. *Linda Schofield* added that for many seniors, there is also an issue of neighborhood safety, which, in turn, ties into having a secure mail box. She encouraged comments and suggestions regarding definitions (e.g., for cost differential) and strategies to address these concerns more specifically.

- *Marc Ryan* pointed out that there usually are clear differences between discount retail and mail-order costs, which could translate into a significant cost differential for SPAPs, if SPAPs pick up these differences in drug costs. States therefore need some protection.

Multiple Residences and Travel

Most SPAPs have policies regarding obtaining medications while beneficiaries are on travel; however, most SPAPs are open only to state residents. CMS allows for disenrollment of members who will be out of their home area for an extended period of time. The primary purpose of the recommendations below is to ensure clarity in the new regulations and policies.

Recommendations

- CMS should require PDP sponsors to notify SPAPs of any disenrollments or enrollment changes of their members.
- CMS should require PDP sponsors to communicate their traveler benefits clearly to members and SPAPs.

Q&A

- *Joan Henneberry* pointed out that these policies are not for wealthy persons (e.g., those with multiple homes around the country); rather, they are targeted toward the typical and special SPAP beneficiaries.

Formulary Issues

Recommendations

- CMS should establish metrics for initial formulary reviews (e.g., the 90 percent rule).
- Risks of SPAPs not coordinating benefits or wrapping around inadequate formularies should be determined. Stronger language is needed for coordinators at the state level. *Linda Schofield* noted that if a formulary is judged inadequate, SPAPs do not have to opt in.
- CMS should establish transition rules during early implementation to ensure continuity of care.
- CMS should reserve authority to review formulary changes to assure continued compliance.
- Enrollees should be protected from adverse clinical outcomes from mid-year formulary changes, such as mid-year deletions. Allowing or requiring 90-day notices for a 3-month phase-in of new formulary drugs will help ensure continuity of care, as will grandfathering of existing patients. *Anne Marie Murphy* pointed out that generics are exempted (i.e., direct equivalents are allowed); deletions at any time are always allowed for safety reasons.
- Mid-year changes affect the SPAP's ability to coordinate benefits. The 30-day restriction is unrealistic for SPAPs.
- The commission agrees with CMS that certain populations' needs for continuity of care trump formulary design. This recommendation does not imply that all special populations are exempted. Rather, it says that the formulary design must accommodate the needs of special populations (e.g., the mentally ill, some nursing home residents); access to an open formulary may be necessary in some cases.

Q&A

- *Marc Ryan* explained that the 90-percent rule is just one benchmark SPAPs can use in meeting CMS's requirement that programs consider cost issues early into implementation of the new regulations.
- In general, the rules for formularies are not very clear.
- *Kim Fox* asked when the commission plans to weigh in on the U.S. Pharmacopoeia (USP) guidelines and recommendations on formularies. *Linda Schofield* stated that the open comment period on these guidelines is closed. However, CMS will review formularies to ensure that they do not discriminate against any conditions. And Linda agreed that broader formularies are important from a clinical standpoint and may be necessary for certain patients or populations. Concern about cost shift to SPAPs must be taken into account. Increases in dual-enrollees and wrap-around programs are often associated with inadequate formularies. Kim noted that these deficiencies are usually related to slippage in drug subcategories. Linda commented that the USP has indicated that it will include recommended subdivisions in its guidelines.

Denials and Appeals

Denials and appeals are very important to SPAPS, and they are key protections for beneficiaries. New formularies are expected to be more restrictive than previous formularies. A full-benefits SPAP will pay for medications that are not on the formulary. Appeals will help increase improve beneficiaries' access to nonformulary drugs and impact copay tiers.

Recommendations

- CMS should recognize SPAPs' authority to encourage enrollees to choose plans that will minimize the likelihood of benefit denial.
- SPAPs should be able to appeal. The regulatory language indicates that SPAPs hold the payment burden. Thus, costs will be absorbed on behalf of patients.
- Pharmacists and physicians should be able to appeal. The regulations do not appear to define a role for pharmacists to appeal.
- Exceptions and appeals process options should be put in place to reduce SPAP liability and patient risk. Doctors can initiate an "exception request." This recommendation will decrease patient risks associated with denials. The commission identified several steps that can be taken to protect patients from denials, including continued access to medications during the appeals process; provide medications to low-income patients during the appeals process; and allowing SPAPs to appeal regarding patterns of denial versus appealing individual cases.
- Written denial notices should be provided, and they should specify reasons for denial and appeal rights.
- Time frames for initial determination should be 2 days. A timely review of denials is essential to ensure continuity of care. SPAPs also will be required to be notified about denials at all phases of the process. The usual 14- to 30-day time frames are unacceptable for persons with chronic illnesses who cannot afford medications, especially if they are denied access to drugs during this interim time period. Bifurcated appeals also should be eliminated under this program.
- Initial denials should be considered coverage determinations, and exceptions should be considered re-determinations.

- Appeal rights should reflect likely duration of use. CMS guidance of 2 months is unreasonable even given typical SPAP beneficiaries. Elimination of bifurcation also is supported with this recommendation.
- Nonformulary drugs approved on appeal should carry the copay of the plan's preferred drug. The copay tier of the preferred drug should apply.

Q&A

- *Dennis O'Dell* noted that the commission discussed at length ways to address the in appropriate denial of appeals. PDP pharmacies have a mechanism in place that includes helping beneficiaries obtain their medications. However, it is not clear when the state can or is supposed to step in with respect to coverage and appeals. Effective communication tools at and through all levels of the process are required. *John Coster* added that a key player in the system, the pharmacist, does not seem to understand fully the appeals process.
- *John Coster* strongly recommended clarification of all components of the appeals process. Who is responsible for initiating an appeal? If pharmacists are identified as the responsible party, does the commission agree with this assignment? What are the legal liabilities of pharmacists and pharmacies in this role?
- *Linda Schofield* relayed the commission's sense that pharmacists want to be involved and play a role in this process. Legal issues, including determination of differences in liability between commercial versus Medicare plans, need significant clarification.
- *Sybil Richard* noted that the commission has spent a considerable amount of time discussing the meaning of denial. Pharmacies and pharmacists generally try to do what they can to ensure patients obtain their script. If the pharmacist pursues all avenues and the patient does not get the script, then this is an initial denial. If the patient eventually gets the drug but has to pay for it, then this is an initial determination.
- *Anne Marie Murphy* emphasized the importance of ensuring that beneficiaries and other parties receive as much information about the denial as possible; having all information is critical to determining which steps to pursue next and to be able to follow up on a denial practically and in a timely manner. Whether a unified process across programs (e.g., SPAPs, PDPs) or a system of different mechanisms would be more effective and efficient could not be determined at this time.

Beneficiary Education

Julie Naglieri, Leader, Claims and Payer Workgroup, noted that concerns about drug discount cards have grown since the roll-out of the cards earlier this year. The recommendations below are designed to ensure that SPAPs are in the loop on all aspects of the new regulations and their implementation.

Recommendations

- PDP should designate SPAPs, where appropriate, to be the primary education/outreach agent for Part D with respect to SPAP enrollments. *James Chase* noted that in some cases, SPAPs work in conjunction with other agencies.
- PDP sponsor communications to SPAP enrollees need to be coordinated with SPAPs. To this end, CMS needs to permit more flexibility to PDPs in the development of outreach materials.

Program Evaluation and Assessment
Dewey Garner, workgroup member, explained that program evaluation and assessment is a new component to regulations representing the largest change in Medicare in 40 years. The commission recommends that CMS embark on a comprehensive program to assess the success of these regulations.
Recommendations

- Evaluation of Part D should include evaluation of the impact on SPAPs and their beneficiaries with respect to access, utilization, claims denials, and patient satisfaction.
- Baseline measurements should be followed by quarterly system measures.
- Metrics should be broken down by PDP/MA-PD (PDP/Medicare Advantage-prescription drug) plan. System metrics should include parameters such as program outcomes, patient demographics, program expenditures, and changes in the prescription mix; data may be stratified by, for example, prescription drug plan.

Q&A

- *Kim Fox* agreed with the commission's assessment of the importance of this component of the new regulations. She recommended also making data available to the public health research community for evaluation of medication use, trends, demographics, and other parameters. Commission members stated that the group will be revisiting these issues, including data collection, use/dissemination, and access.

Program Redesign and Part D Coordination
Robert Power explained that some SPAPs may choose to simplify their relationship with PDPs by paying premiums rather than claims. The following recommendations, which go to the principle of giving SPAPs more flexibility, address how CMS should clarify various aspects of this issue.
Recommendations

- CMS should clarify that assistance can apply to premiums for basic, basic alternative, or basic enhanced coverage.
- CMS should clarify that all cost sharing paid for through an SPAP premium should count toward TrOOP.
- CMS should establish Federal base premiums for SPAPs to use in buying supplemental coverage.
- Customized supplemental coverage should be available.

Q&A

- *Linda Schofield* explained that these recommendations are based on the concern that PDPs can establish their own prices at the level of their choosing. The commission supports establishing standards like those set in Federal plans.

Commission Recommendations: Coordination of Benefits (COB)

Julie Naglieri explained that as SPAPs consider coordinating benefits at the point of sale (POS), it is important to determine how to ensure a smooth transition for beneficiaries and

that SPAP expenses are covered. These goals require timely exchange of information among all parties involved in the system.

Centralized Data System

The commission's recommendations shift the burden of information sharing from beneficiaries to CMS, which would be required to collect data in a timely fashion. The recommended approach avoids multiple layers of exchanges and should increase efficiency in communication.

Recommendations

- CMS should establish a centralized data system that will collect accurate coverage information, provide up-to-date coverage information for each beneficiary to all parties, and support real-time coordination of benefits.
- SPAPs would routinely exchange enrollee information with other parties, including pharmacies.

TrOOP Tracking

PDPs are responsible for tracking TrOOP, and such tracking is required to commence as soon as the new program is launched.

Recommendation

- The centralized data system will allow Part D plans to know who their SPAP enrollees are and to track TrOOP in real time. These features will avoid additional burden on beneficiaries and can be built upon well-established efficiencies and technologies developed in the pharmacy industry.

Q&A

- Other options are under discussion by the industry, for example, developing or incorporating features to enhance the system. *Dennis O'Dell* said the commission welcomes additional details on these enhancements. Having a coordinated system approach, which should decrease confusion and increase utilization and efficiency, is preferred.
- *Roy Bussewitz* summarized key components of and differences between how prescription claims currently are processed, how they will be processed by CMS per Medicare Part D, and how they may be processed using a single point of contact system (SPOCS) being developed by the National Association of Chain Drug Stores (NACDS). The NACDS SPOCS incorporates plan eligibility, TrOOP and copay information, COB, and drug utilization review (DUR) information. The system provides separate claims responses in real-time to pharmacies and patients (through pharmacies).

Technical Advisory Committee

Recommendations

- A Technical Advisory Committee should be established, and it should be in place beyond the initial implementation of Part D.
- The committee would provide recommendations and develop requirements for a reliable, efficient, recipient-friendly electronic system of COB.

Q&A

- The SPATC will be disbanded after submission of its report and recommendations to the President and the Congress at the end of the year. The Technical Advisory Committee will continue the commission's work, among other tasks and activities.

PDP Sponsor Requirement

Recommendations

- PDP sponsors should be ***required*** to coordinate benefits with SPAPs.
- CMS should establish clear guidelines and requirements for this coordination.

Recommended COB Guidelines

Recommendations

- Establish standards for an identification card, such as those of the National Council for Prescription Drugs Program (NCPDP), which the SPATC endorses.
- Establish a Universal Payer ID. A universal ID will help coordinate and standardize data under one umbrella and facilitate communication across parties.
- Establish payer-to-payer transmissions.
- Set up a retroactive recovery process.
- PDP sponsor claim response should inform pharmacies of SPAP coverage.
- SPAPs should not have to pay PDP sponsors for the COB required by law.

Q&A

- *Kim Fox* asked if these guidelines also apply to or are required of MA-PDs and PDPs. MA-PDs will most likely follow these or similar guidelines. It was noted, however, that MD-PDs, unlike SPAPs, provide an actuarial equivalent. There was some concern that if all programs are not required to follow the same guidelines that other parties may not want to participate in the SPAP system or network.
- *Jay Currie* suggested establishing a simpler rather than a more complex system that would identify the role(s) of each party and determine specific coverage of an individual beneficiary. CMS could facilitate coordination of stakeholders.

Education of Beneficiaries, Prescribers, and Pharmacies

Recommendations

- CMS should fund, develop, and deliver education programs to facilitate understanding of program operations for beneficiaries, prescribers, and pharmacists.
- CMS should facilitate the coordination of communication among stakeholders.

Q&A

- *John Coster* suggested that CMS directly fund these activities through grants to the states.
- *Jay Currie* recommended that separate funds should be dedicated to meeting, education, and enrollment to make the system work for beneficiaries.
- *James Chase and others* stated that the commission needs to be more explicit as to what CMS needs to do (e.g., recommend that CMS earmark "x" amount of dollars to the states for professional education).
- *Susan Reinhard* inquired about coordinating messages to beneficiaries across all sources. Joan Henneberry commented that an earlier recommendation gave SPAPs more control

over information dissemination; however, the commission stepped back somewhat from that position and from "overloading" beneficiaries with information.

Miscellaneous Recommendations

The following commission recommendations did not seem to fit into any of the three main categories.

Recommendation: CMS should form an SPAP advisory committee, separate from the technical advisory committee, to serve as a vehicle for ongoing communication between CMS and SPAPs.

Recommendation: CMS should not allow involuntary disenrollment from PDPs for disruptive behavior. If CMS does not change this policy, it should implement an appeals process for participants who are involuntarily disenrolled from a PDP.

Q&A

- What is "disruptive behavior," and how is it defined for the purposes of CMS's policy?

Recommendation: "Institutionalized duals" should be broadly defined for the purposes of copay relief, to exempt special populations.

Q&A

- *Marc Ryan* noted that exempt populations are tied to SSA definitions. Further guidance may be needed to address and implement this recommendation, which would target persons in institutionalized care, the mentally retarded, persons with very low personal needs allowances, and persons in residential facilities who cannot afford cost shares. For example, an allowance of $130/month would most likely be considered insufficient to cover copays for many people in these target groups. The recommendation should also address formularies and cost sharing, perhaps through separate special-needs allowances.

Recommendation: SPAPs need to maintain ongoing communication with local SSA offices to improve and coordinate all aspects of communication.

Unresolved Issues

The commission continues to discuss and work on final language for the following two issues, which may or may not be included in the commission's final report.

Unresolved issue: CMS should anticipate the critical role that pharmacists may play in counseling beneficiaries regarding clinical concerns in their choice of plans. This role should be balanced against COB issues.

Unresolved issue: SPAPs should have the option to act as a PDP for SPAP members. This issue was woven into much of the commission's discussions in developing the draft recommendations, especially with respect to the role that SPAPs might play in their own state. Legal and financial issues are two key areas that would need to be addressed and well delineated. This issue also ties into the commission's overarching principle that states be as

flexible as possible in designing and implementing a framework that allows SPAPs to coordinate with PDP sponsors.

Q&A

- *Marc Ryan* noted that his state is lobbying Congress to allow PMPMs to cover beneficiaries. Congress's general response has been that PDPs are too costly and too liberal regarding formularies. This perspective may apply in most cases, but it should be a viable option when necessary to meet certain beneficiaries' needs; in some cases, this option could actually drive down some costs and serve to wrap-around a cost-effective benefit. *Linda Schofield* added that this approach could also serve as a temporary (6- to 12-month) fix, particularly during the roll-out and enrollment phases preceding the launch of the full program in January 2006.
- *Kim Fox* suggested adding the issues of rebates and transparency by PDPs to states regarding rebate receipts, which, in turn, could impact potential savings. An ongoing concern among some parties is that PDPs can accrue rebates, but the amounts of those rebates are unknown to the SPAPs. PDPs are required to report rebates and percentages to CMS but states do not receive that information despite being part of the public system. *James Chase* commented that the system allows the CMS to get this information to set rates. Limitations on requirements for information sharing in this case helps maintain the private and proprietary nature of these data; it is not clear how privacy would be maintained if the information is shared with all 50 states. *Linda Schofield* and *Kim Fox* countered by noting that the states, like CMS, also negotiate rates. *Joan Henneberry* noted that the commission discussed this issue but was not able to come to a consensus on a recommendation. For example, the commission could not reach consensus on questions such as how rebates and transparency would affect beneficiaries and SPAPs directly and how would such an approach be implemented to balance the needs and interests of all parties.

Unresolved issue: The creation of new SPAPs in states without SPAPs. This issue best complements the principle of flexibility and is supported by the commission. Thus, it may actually be considered more of a resolved than an unresolved issue.

Closing Remarks

Ms. Henneberry adjourned the public session and invited commission members to remain for a closed session to review the day's discussions and comments and to detail next steps. They will work diligently over the next 3 months to produce and deliver their final report to the President and the Congress by January 1, 2005. Final writing and editing is expected to begin in early November, with one or two interim drafts developed for internal review by the commission before printing of the final report in December. The final report will provide background on the new regulations and details of the commission's discussions and deliberations. It will include the commission's final recommendations and a detailed proposal to address the unique transitional issues facing SPAPs and their beneficiaries as a result of implementation of Medicare Part D. Unresolved issues and minority opinions will also be addressed in the final report.

Meeting was adjourned at 3:30 p.m.